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EXAMINER	
MERTZ, PREMA MARIA	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/616,263	JACOBS ET AL.	
	Examiner	Art Unit	
	Prema M. Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-24* is/are pending in the application.

4a) Of the above claim(s) *19 and 22-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-18,20 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/8/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

1. Applicant's election of Group I (claims 14-18, 20-21) on 8/23/05 is acknowledged.

Claims 1-13 have been canceled (8/23/2005).

Claims 19, [illegible] are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Election was made **without** traverse in the reply filed on 8/23/2005.

Claims 14-18, 20-21 are under consideration by the Examiner.

Specification

2. According to the priority statement of 7/8/2003, it appears that priority is being claimed to a large number of provisional applications. These applications appear to be drawn to unrelated subject matter and are either not available for consideration or for which consideration to determine support for the instantly claimed subject matter would require an undue burden. Accordingly, the subject matter defined in claims 14-18, 20-21 has an effective filing date of 8/13/1999, that of parent application 09/374,046.

Applicants are requested to provide the serial number and specific page numbers of any parent application to which priority is desired which specifically supports the particular claim limitation for each and every claim limitation in all the pending claims which applicant considers to have been in possession and fully enabled prior to 8/13/1999.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 16-17 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter.

The claims embrace the naturally occurring product in nature. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). Therefore, the claims must be limited such that they do not encompass the product in nature. However, since it would that Applicants do not intend to claim a naturally occurring product, amending the claims to recite a recovery and/or purification step will obviate this rejection, i.e. isolated or purified.

Claim rejections-35 U.S.C. 101-utility rejection

4. Claims 14-18, 20, 21 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The invention encompassed by claims 14-18, 20, 21 has no apparent or disclosed patentable utility. This rejection is consistent with the current utility guidelines, published on 1/5/01, 66 FR 1092. The instant application has provided a description of an isolated polynucleotide, but does not disclose a specific and substantial biological role of the protein encoded by this polynucleotide or the significance of the protein. There is no biological activity, phenotype, disease or condition, ligand, binding partner, or any other specific feature that is disclosed as being associated with the mature polypeptide. The

mere identification of the polypeptide is not sufficient to impart any particular utility to the polypeptide encoded by the claimed polynucleotide without any information as to the specific properties of the polypeptide.

The instant claims are drawn to a nucleic acid encoding a polypeptide, which has an as yet undetermined function or biological significance. Until some actual and specific significance can be attributed to the protein identified in the specification as having homology to the "chaperonins" (page 269, lines 1-10), the instant invention is incomplete. The specification on page 269, lines 2-4, recites:

"Analysis of the amino acid sequence of the predicted pp314-19 protein revealed the cpn60-TCP1 signature (at amino acids 29-570 of SEQ ID NO:30) which has some ATPase activity and is indicative of chaperonins. A P-loop motif - a common motif in ATP- and GTP-binding proteins - is found around amino acid 200 of SEQ ID NO:30."

However, the instant specification does not disclose any information regarding functional characteristics or the biological activity of the instantly claimed protein. The specification does not demonstrate that the claimed polynucleotide encoding the polypeptide of SEQ ID NO:30 actually displays any activity such as ATP and GTP binding. In the absence of knowledge of the specific biological significance of the claimed polynucleotide encoding the protein of SEQ ID NO:30, there is no immediately obvious patentable use for it. Since the instant specification does not disclose a "real world" use for the nucleic acid encoding the protein then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 USC § 101 as being useful.

A protein of unknown function would have utility if it can be employed as an indicator of a diseased state or of the presence of a disorder. The only disclosed function for the polynucleotide encoding the protein of the instant invention is that it has a signature sequence indicative of chaperonins (see page 269, lines 2-4). However, Applicants have failed to demonstrate the biological activity of the protein encoded by the claimed polynucleotide. Applicant is only required to identify one substantial credible utility and the employment of this polynucleotide only as the subject of further research does not satisfy the utility requirement of 35 U.S.C. § 101 because the courts have interpreted this statute as requiring an invention to have "substantial utility" "where specific benefit exists in currently available form". The disclosure that the polynucleotide of the instant invention encodes a possible chaperonin protein is not a substantial or specific utility.

The state of the art is such that functional information can be automatically derived from structural information only to a limited extent, (see Sklonick et al, Nature Biotechnology, Vol.18, No.3, pages 283-287, especially page 286, middle of column 1). Sklonick et al also state that knowledge of the overall structure or domain family is still not enough to confidently assign function to a protein. Therefore, there is little doubt that, after further characterization, the protein is found to be member of the chaperonin family, the claimed polynucleotide would have a specific, substantial and credible utility. However, further characterization is part of the invention and until it had been undertaken, the claimed invention is not supported by a specific asserted utility or a well established utility. The claimed invention is directed to a polypeptide of as yet undetermined function or biological significance. Thus, since there is no biological

activity disclosed for the protein encoded by the claimed nucleic acid, the claimed invention is not supported by either a specific and substantially asserted utility or a well established utility.

Claim rejections-35 USC § 112, first paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-16, 20, 21 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The instant specification does not disclose a biological activity for the claimed polypeptide, therefore, there is no specific and substantial asserted utility or well established for the claimed polypeptide.

Claim rejections, 35 U.S.C. § 112, first paragraph

5a. Claims 14 and 21, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make use the invention.

The deposit of biological material is considered by the Examiner to be necessary for the enablement of the current invention because the claims require availability of the

deposit. Elements required for practicing a claimed invention must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. When biological material is required to practice an invention, and if it is not so obtainable or available, the enablement requirements of 35 USC §112, first paragraph, may be satisfied by a deposit of the material. See 37 CFR 1.802.

The specification does not provide a repeatable method for obtaining ATCC Deposit No. 98835 and it does not appear to be a readily available material. The ATCC® deposit in full compliance with 37 CFR §§ 1.803-1.809 would satisfy the requirements of 35 USC §112, first paragraph.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or Declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

(a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;

(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803-1.809 for additional explanation of these requirements.

5b. Claims 14-18, 20-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide encoding a full-length protein of SEQ ID NO:30 or the full-length protein deposited under accession number ATCC 98835, does not reasonably provide enablement for an isolated polynucleotide encoding the mature form of the protein of SEQ ID NO:30 or the mature form of the protein deposited under accession number ATCC 98835. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 14, sub-parts (e)-(f), encompass an isolated polynucleotide encoding the mature form of the protein of SEQ ID NO:30 or the mature form of the protein deposited under accession number ATCC 98835. The specification does not disclose the specific sequence of the mature protein recited in claim 14. The full-length protein has the sequence of SEQ ID NO:30 as disclosed in the specification, which is not equivalent to the mature polypeptides recited in claim 14, sub-parts (e)-(f). The skilled artisan cannot envision the detailed chemical structure of the encompassed protein and, therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it.

The invention is drawn to a polynucleotide encoding a protein that occurs naturally since it is encoded by a naturally occurring polynucleotide. It is acknowledged that the skill of the artisan in the molecular biology art is high. It is further acknowledged that in some cases, leader/signal sequences are readily identifiable because of high conservation of certain such sequences across species, families or groups of proteins. Due to the lack of guidance in the prior art and current application, one skilled in the art could not predict if the mature form of the protein differs from the full-length form, and if it does, how. The breadth of the claims comes from encompassing a protein, the form of which is not known, and the possibility that more than a single mature protein exists. This possibility is acknowledged by Applicants, because the specification on page 268, lines 12-18, recites:

"What applicants presently believe to be the proper reading frame and the predicted amino add sequence of the pp314-19 protein corresponding to the foregoing nucleotide sequence is reported in SEQ ID NO:30. Amino acids 147 to 159 of SEQ ID NO:30 are a possible leader/signal sequence, with the predicted mature amino acid sequence beginning at amino acid 160; amino acids 238 to 250 of SEQ ID NO:30 are also a possible leader/signal sequence, with the predicted mature amino add sequence beginning at amino acid 251. Due to the hydrophobic nature of these possible leader/signal sequences, each is likely to act as a transmembrane domain should it not be separated from the remainder of the pp314-19 protein."

As written in the claims, the mature form is described as a single compound, however, there is precedence in the prior art for full-length unprocessed proteins to be processed into more than one unique compound. It is not known whether this protein has only a single precursor form or whether it goes through several rounds of signal sequence processing to produce several mature forms as is the case with, for example Neurophysin I and II, which are produced form prepropressophysin and prepro-oxyphysin, respectively (Ganong, 1995, page 220, Fig. 14-11) and pro-opiomelanocortin, which is cleaved during processing to form 8 functional peptides (Creighton, 1984, page 71, Fig. 2-6), or cholecytokinin-pancreozymin (CCK), which undergoes multiple processing steps such that prepro-CCK is processed into many fragments (Ganong, 1995, page 446). There are also cases of protein processing in which the mature form differs from the full-length most significantly in the absences of amino acids internal in the protein (see for example Crieghton, 1984, page 72, Fig. 2-7 of chymotrypsinogen A). Therefore, in the instant case one cannot predict what that mature form(s) will be. For

these reasons, it does not appear that the inventors were in possession of the claimed invention at the time of filing.

5c. Claims 16-17 are is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a host cell in culture comprising a polynucleotide with the sequence as set forth in SEQ ID NO: 29, does not reasonably provide enablement for *in vivo* transfection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The specification discloses that the nucleic acids of the current invention can be expressed in a wide variety of host cell types, including cells within a host animal (page 347). However, there are no actual or prophetic examples that disclose how to make or use host cells that comprise a DNA sequence as set forth in SEQ ID NO: 29 in an animal. The Examiner cites Eck & Wilson (page 8 1, column 2, second paragraph to page 82, column 1, second paragraph) who report that numerous factors complicate *in vivo* gene expression which have not been shown to be overcome by routine experimentation. These include, the fate of the DNA vector itself (volume distribution, rate of clearance into the tissues, etc.), the *in vivo* consequences of altered gene expression and protein function, the fraction of vector taken up by the target cell population, the trafficking of the genetic material within cellular organelles, the rate of degradation of the DNA, the level of mRNA produced, the stability of the mRNA produced, the amount and stability of the protein produced, and the protein's compartmentalization within the cell, or its secretory fate, once produced. Since the instant disclosure does not address any of the

methods necessary to make a host cell in an animal, which comprises the polynucleotide of interest, the claims as written are not enabled. This rejection could be overcome by addition of the limitation wherein the host cells are "isolated".

5d. Claims 14-18, 20-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide encoding a protein of SEQ ID NO:30, does not reasonably provide enablement for an isolated polynucleotide encoding a species homologue of the protein of SEQ ID NO:30 or a polynucleotide encoding a protein comprising a fragment of the amino acid sequence of SEQ ID NO:30 having biological activity, the fragment comprising eight continuous amino acids of SEQ ID No:30. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 14, sub-part (j), is drawn to a polynucleotide encoding a polypeptide, which is a species homologue of the protein of SEQ ID NO:29. The specification provides only sequence data to allow one to characterize the protein. Many distinct proteins may share the same activity, so that even if one were to determine a biological activity of the protein, for example inducing eosinophil accumulation, many distinct proteins would have this activity (e.g. many different cytokines like RANTES and MIP-1α). As a result, if one were to isolate a protein from a different species that had the same activity, one could not reasonably predict if the isolated protein was a species homologue of the original protein because one could not determine if the sequence difference between the original and isolate were due to species differences or to the proteins being

non-homologous but sharing the same activity. With respect to the claimed polynucleotide encoding a protein of SEQ ID No:30, since no specific biological activity or an assay for demonstrating the biological activity of the protein has failed to be described, it would be undue experimentation to conduct every assay in the hopes of identifying a specific activity, and no guidance is provided to enable a skilled artisan to predict which activity the protein is likely to have.

There is no information about how to identify a "suitable" probe or primer to obtain a "species homologue". Additionally species homologues often display low sequence identity so that identification based solely on sequence similarity is impossible. Under such common circumstances, if one cannot test for the expected activity of the encoded putative species homologue, then it is impossible to identify species homologues. For example in The Cytokine Facts Book (1994), Robin Callard and Andy Gearing. Academic Press Inc. San Diego, CA, the amino acid sequence of IL-2 (interleukin-2) from human compared to mouse differs by 16 amino acids in length (page 39, table) and share only about 60% identity (page 39, "Crossreactivity" section). Based solely on sequence, it would be clearly impossible for one skilled in the art to identify the mouse and human proteins as species homologues; however, when one is able to compare a known or putative activity (page 39, "Bioassays" section"), identity can be confirmed.

Furthermore, Reeck et al. (line 1-2) point out, ""Homology" has the precise meaning in biology of "having a common evolutionary origin,"...".

It is stated at the top of column 2 that:

A similarity, then, can become a fully documented, simple fact. On the other hand, a common evolutionary origin must usually remain a hypothesis, supported by a set of arguments that might include sequence or three-dimensional similarity. Not all similarity

connotes homology but that can be easily overlooked if similarities are called homologies. Thus, in this third case, we can deceive ourselves into thinking we have proved something substantial (evolutionary homology) when, in actuality, we have merely established a simple fact (a similarity, mislabeled as homology). Homology among similar structures is a hypothesis that may be correct or mistaken, but a similarity itself is a fact, however, it is interpreted.

Reeck et al. provided emphasis to the above reasons for not being able to identify, if one is able to isolate candidates, species homologues as claimed because of the lack of guidance and information in the current specification.

The specification only enables polynucleotides encoding a protein of amino acid sequence set forth in SEQ ID NO:30, and is not enabled for a polynucleotide encoding a polypeptide having an amino acid sequence anything less than what is disclosed in SEQ ID NO:30. The issue in the instant case is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. The recitation of "the fragment comprising eight contiguous amino acids of SEQ ID NO:30..." in claim 14(h) is not a sufficient structural limitation and broadly encompasses any polynucleotide encoding a protein comprising 8 contiguous amino acid sequences recited in the claims. Because of the presence of the term "comprising" in claim 14(h), the claim encompasses a polynucleotide encoding a polypeptide comprising any 8 contiguous amino acids from SEQ ID NO:30, and therefore the claim encompasses polypeptide embodiments encompassing any other 562 amino acid sequences or more in addition to these 8 contiguous amino acids. The number of polypeptide embodiments in this case are over 5×10^{207}.

Furthermore, the instant specification does not provide the guidance needed to use these polynucleotides as claimed. Even if Applicants recited a functional limitation for the polynucleotide encoding the polypeptide in the instant claims, Applicants have not taught how to make and use the instant polynucleotides encoding polypeptides with the stretch of 8 contiguous amino acids as recited in claim 14 (h). The instant specification does not teach which polynucleotides encoding polypeptides would predictably be associated with a biological function. The instant claims are not limited to naturally-occurring compounds and the instant specification does not provide a description of a repeatable process of producing a polynucleotide encoding a polypeptide comprising at least 8 contiguous amino acids of SEQ ID NO:30. To practice the instant invention in a manner consistent with the breadth of the claims would not require just a repetition of the work that is described in the instant application but a substantial inventive contribution on the part of a practitioner which would involve the determination of those amino acid residues of the disclosed naturally-occurring protein, which are required for functional and structural integrity of the protein. It is this additional characterization of the protein that is required in order to obtain the structural data needed to permit one to produce the claimed polynucleotide encoding a protein, which meets the structural requirements of the instant claims that constitutes undue experimentation.

5e. Claims 14-18, 20-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 14, sub-part (i) recites "an allelic variant of any one of the polynucleotides....". The specification and claims do not indicate what distinguishing attributes shared by the members of the genus. The specification and claims and do not place any limit on the number of nucleotide substitutions, deletions, insertions and/or additions that may be made. Thus, the scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members are permitted. The specification and claims do not provide any guidance as to what nucleotide changes should be made. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, a polynucleotide set forth, for example, in SEQ ID NO:29 alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicants were not in possession of the claimed genus of allelic variants of the polynucleotide of SEQ ID NO:29.

Claims 15-18, 20-21, are rejected under 35 U.S.C. 112, first paragraph, insofar as they depend on the above rejected claim for their limitations.

Claim rejections-35 USC § 112, second paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-18, 20-21, are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 is vague and indefinite for several reasons.

Claim 14(h) is unclear because it is unclear what the biological activity would be if the biological activity of the protein is one that is as yet unknown.

Claim 14 (k)-(l) recites "hybridizes under stringent conditions", which is a relative and conditional term and renders the claim indefinite. Furthermore, some nucleic acids which might hybridize under conditions of moderate stringency, for example, would fail to hybridize at all under conditions of high stringency. The metes and bounds of the claim thus cannot be ascertained.

Claim 20 is vague and indefinite because it is dependant on non-elected claim 19. Appropriate correction is requested.

Claims 15-18, 21 are rejected as vague and indefinite insofar as they depend on the above rejected claims for their limitations.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the

> treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

7a. Claims 14-18, 20 are rejected under 35 U.S.C. 102(e) as being anticipated by WO 99/31236 (1999).

The reference teaches the cloning of a secreted protein, which has 17.1% homology to the nucleic acid of nucleotide sequence set forth n SEQ ID NO:29 (see Sequence Comparison **A**). Therefore, the nucleic acid encoding the secreted protein would hybridize to SEQ ID NO:29 under stringent conditions. The nucleic acid encoding the secreted protein was cloned into a vector and transfected into host cells (see abstract; page 6, lines 14-20). Therefore, the cDNA disclosed in the reference meets the limitations of claims 14-18, 20.

Conclusion

Claims 14-18, 20-21 are rejected.

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For

more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz

Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
September 18, 2005